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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,667	04/30/2001	Philip Cohen	002.00041	3701

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,667

Applicant(s)

COHEN ET AL.

Examiner

Jeffrey E. Russel

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/091,763.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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1. Claims 1-14 and 20-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20.

Applicant's election with traverse of the invention of Group II and the species PKB in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is a technical relationship among the claimed inventions involving one or more technical features. This is not found persuasive because the independent claims 1, 2, and 26 do not avoid the prior art. In particular, Applicants admit at page 3, lines 15-23, that insulin is an activator of PKB. Claims 1 and 2, which are drawn to uses of activators of PKB, e.g., to combat diabetes, are anticipated by the well-known use of insulin to treat diabetes. Claim 15 does not avoid the prior art, as discussed in the rejections set forth below. Claim 26 is anticipated by the known enzyme MAPKAP kinase-2, which is capable of reacting with residues 308 or 473 of PKB to phosphorylate these residues (see the Alessi et al article, EMBO J., Volume 15, pages 6541-6551). With respect to the inventions of Groups II and IV, Applicants admit at page 1, line 24 - page 2, line 3, and at page 3, lines 20-25, that the prior art has already identified or determined that the agent or substance insulin is able to influence the activity of GSK3 and PKB. Because these claims are anticipated by the prior art, there is no special technical feature which defines a contribution which each of the inventions makes over the prior art, and therefore there is a lack of unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

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2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should mention GSK3 and PKB.

3. The disclosure is objected to because of the following informalities: There is no Brief Description of the Figures as required by 37 CFR 1.74. SEQ ID NOS need to be inserted after each of the amino acid sequences recited in Figure 18, or more preferably in the Brief Description of Figure 18. See 37 CFR 1.821(d). At page 2, line 30, "Two" should be changed to "Three". At page 29, line 22; page 30, line 32; and page 31, line 13; the figure numbers should be checked. Appropriate correction is required.

4. Claims 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent that claims 15-19 depend upon claim 10, claims 15-19 are indefinite because the phrase "functional equivalent" in claim 10 is indefinite. The phrase "functional equivalent" in claim 10 is indefinite because the claim does not specify the function which must be equivalent and it is not clear in which function or functions a compound must be equivalent to the peptide of SEQ ID NO:58. For example, the solubility of a compound in a solvent, the ability of a compound to be hydrolyzed by a protease, or the ability of a compound to be administered therapeutically, might constitute equivalent functions. Claim 15 refers to "a peptide as claimed in claim 10" and claim 16 refers to "the peptide". However, claim 10, upon which claims 15 and 16 ultimately depend, is drawn to a peptide "or a functional equivalent of such a peptide". Claim 10 does not require the functional equivalent itself to be a peptide.

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Accordingly, it is not clear if claims 15 and 16 embrace using a functional equivalent of the peptide of claim 10, rather than the peptide of claim 10 per se.

5. Instant claims 15-19 are not entitled under 35 U.S.C. 119 to the benefit of the filing date of priority application GB 9526083.2 because the GB '083.2 priority application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a peptide as claimed in claim 10 or functional equivalents of such a peptide, does not disclose determining the phosphorylation state of one or both of amino acids 308 and 473 on PKB, and does not disclose a test substance which is an isoform of PKB. Instant claims 15-19 are not entitled under 35 U.S.C. 119 to the benefit of the filing date of priority application GB 9610272.8 because the GB '272.8 priority application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a peptide as claimed in claim 10 or functional equivalents of such a peptide and does not disclose a test substance which is an isoform of PKB. Instant claims 15-19 are not entitled under 35 U.S.C. 119 to the benefit of the filing date of priority application GB 9615066.9 because the GB '066.9 priority application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a peptide as claimed in claim 10 or functional equivalents of such a peptide. Accordingly, the Cross et al article (Nature, Vol. 378, pages 785-789) and the Alessi et al article (EMBO J., Vol. 15, pages 6541-6551) are available as prior art against the instant claims under 35 U.S.C. 102(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

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7. Claims 15, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Burgering et al article. The Burgering et al article teaches an assay in which a test substance such as insulin, PDGF, EGF, and bFGF is contacted with PKB and myelin basic protein, which corresponds to a functional equivalent of the peptide recited in instant claim 10. MBP is deemed to be a functional equivalent of the peptide recited in instant claim 10 because MBP is also capable of being phosphorylated by PKB. Contacting occurs in the presence of $MgCl_2$, a source of divalent cations, and ATP. Phosphorylation of the MBP is detected by autoradiography. See, e.g., the abstract and Figure 1.

8. Claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Franke et al article in view of the Kootstra et al article. The Franke et al article teaches an assay in which PDGF and optionally N17Ras or wortmannin, PIP, PI, and PIP_2 , which correspond to Applicants' test substance, are contacted with Akt, i.e. PKB, and various histones or myelin basic protein, which correspond to a functional equivalent of the peptide recited in instant claim 10 because the histones and MBP are also capable of being phosphorylated by PKB. The extent of phosphorylation of the substrate can be determined with a Phosphorimager. See, e.g., Figures 1, 6, and 7, and Table 1. The Kootstra et al article teaches that histone H2B comprises the partial sequence Arg-Ser-Arg-Lys-Glu-Ser-Tyr (see residues 29-35), and therefore the histone H2B substrate taught by the Franke et al article inherently includes Applicants' amino acid sequence SEQ ID NO:58.

9. Claims 15, 16, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by the Cross et al article (Nature, Volume 378, pages 785-789). The Cross et al article teaches contacting PKB with test substances such as insulin, wortmannin, and LY 294002, and then

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contacting the PKB with the substrate Crosstide, which is a peptide including Applicants' SEQ ID NO:58. The extent of phosphorylation of the substrate is determined in terms of units of protein kinase activity. PKB is significantly more active towards Crosstide than it is towards histone or MBP, other known PKB substrates. See, e.g., page 785, column 2, first full paragraph, and Figures 1 and 2.

10. Claims 15, 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being obvious over the Burgering et al article as applied against claims 15, 16, 18, and 19 above, and further in view of the Cross et al article (Nature, Volume 378, pages 785-789). The Burgering et al article does not teach a substrate which includes Applicants' SEQ ID NO:58. The Cross et al article teaches that PKB has higher activity towards the substrate Crosstide, which is a peptide including Applicants' SEQ ID NO:58, than it does towards MBP. See Figure 2. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the Crosstide substrate of the Cross et al article as the substrate in the assay of the Burgering et al article because the resulting assay would have been expected to be more sensitive because of PKB's higher activity towards the Crosstide substrate.

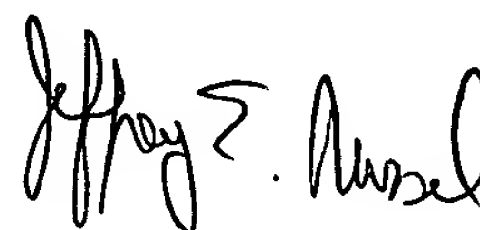
11. Claims 15-19 are rejected under 35 U.S.C. 102(a) as being anticipated by the Alessi et al article (EMBO J., Vol. 15, pages 6541-6551). The Alessi et al article teaches contacting PKB with test substances such as MAPKAP kinase-2, insulin, IGF-I, and wortmannin, and then contacting the PKB with the substrate Crosstide, which is a peptide including Applicants' SEQ ID NO:58. The extent of phosphorylation of the substrate is determined in terms of units of protein kinase activity. Phosphorylation at residues 308 and 473 of PKB is determined. See,

e.g., the Abstract; Figure 7; page 6546, column 2, last paragraph; and page 6549, column 2, last full paragraph.

12. The Lessi et al article (FEBS Lett., Volume 399, pages 333-338), is deemed to be essentially duplicative of the references applied above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

March 26, 2003